

WHAT IS CLAIMED IS:

1. A method of preparing a mixed formulation of sustained release microspheres by a continuous one-step process, comprising:

5 preparing two to four different fluids for preparation of the sustained release microspheres containing a biodegradable polymer and a peptide drug; and

continuously supplying the mixed fluids from the two to four different fluids to a dryer via a single spray nozzle by controlling the mixing ratios of the fluids according to the time to dry the fluids.

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2. The method as set forth in claim 1, wherein the fluids contains the biodegradable polymer, the peptide drug, an additive and a solvent with different compositions of one or more of the components.

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3. The method as set forth in claim 1, wherein the sprayed fluids are dried by a spray-drying method, a spray freeze-drying method, or a supercritical fluid-based drying method.

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4. The method as set forth in claim 1, further comprising dispersing the sustained release microspheres in a solution containing a dispersion excipient and freeze-drying a resulting solution.

5. The method as set forth in claim 1, wherein the peptide drug is selected from among peptides of 2 to 60 amino acid residues in length and salts thereof.

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6. The method as set forth in claim 5, wherein the peptide drug is selected from among luteinizing hormone releasing hormone (LHRH) analogs, octreotide and salts thereof.
- 5 7. The method as set forth in claim 6, wherein the LHRH analogs are selected from among triptorelin, leuprolide, goserelin, nafarelin, buserelin, histrelin and salts thereof.
- 10 8. The method as set forth in claim 1, wherein the biodegradable polymer is selected from polylactide, polyglycolide, poly(lactide-co-glycolide), polyorthoesters, polyanhydrides, polyamino acids, polyhydroxybutyric acid, polycaprolactone, polyalkylcarbonate, lipids, fatty acids, waxes, and derivatives and mixtures thereof.
- 15 9. The method as set forth in claim 8, wherein the biodegradable polymer is selected from polylactide and poly(lactide-co-glycolide).